

United States Department of Agriculture Agricultural Marketing Service STOP 0248 – Room 2628-S 1400 Independence Avenue SW. Washington, D.C. 20250-0248 MGC Instruction 613 September 18, 2002 Page 1 of 6

Effective October 1, 2002 EXAMINATION AND SAMPLING PROCEDURES FOR MICROBIOLOGICAL REQUIREMENTS

Purpose

This Instruction sets forth Meat Grading and Certification (MGC) Branch policies and procedures for the selection, collection, preparation, shipment and analysis of sample of products purchased by the United States Department of Agriculture (USDA).

Policy

It is USDA policy to analyze ground, uncooked, meat products intended for use in the National School Lunch Program for Standard Plate Count, Total Coliforms, *E. coli*, *E. coli*, *E. coli* O157:H7, *Salmonella*, and Coagulase Positive *Staphylococci*.

Additionally, it is the policy of the MGC Branch to select samples in accordance with universally recognized protocols, maintain sample integrity, and prepare samples for laboratory analysis in accordance with the appropriate chapter of the Compendium of Methods for the Microbiological Examination of Foods (third edition) published by the American Public Health Association and the "USDA/FSIS Microbiological Laboratory Guidebook, 3rd edition/1998, Chapter 5" for *E. coli* O157:H7 requirements.

Scope

This Instruction applies to any processor or producer who supplies ground, uncooked, meat products for USDA contracts as a contractor or subcontractor.

Responsibilities

1. Contractors will:

- a. Provide a plant employee trained and experienced in microbiological sampling; knowledgeable of the documents referenced in the Policy section of this Instruction; and capable of preparing microbial samples under the supervision of MGC Branch personnel.
- b. Provide a Food Safety and Inspection Service (FSIS)-approved sanitary work area and sampling equipment, including a sanitized table, knives, spatulas, and other sample collecting devices.

Note: Knives, spatulas, etc., shall not be sterilized with chemical sanitizers. Chemical sanitizers may be used to sanitize work spaces and table tops, provided the area rests for a minimum of 1-hour prior to sample collection.

c. Provide an FSIS-approved water sterilizer capable of maintaining water at a temperature of 180° Fahrenheit (F) (82.2° Celsius (C)) within easy access of the sample preparation facilities and equipment.

- d. Provide self-closing, sterile plastic bags that are suitable for collection of microbial samples.
- e. Provide polyfoam mailing containers and refrigerant packs or dry ice for shipment of samples to the Agricultural Marketing Service (AMS) Laboratory.
- f. Provide a freezing facility capable of rapidly freezing samples to 0° F (-17.8° C) or lower within 24 hours. Liquid nitrogen or other quick freeze processes are not acceptable.
- g. Pay for all shipment and analysis charges for samples forwarded to the AMS and FSIS laboratories.
- h. Provide storage space for the sampling supplies furnished by FSIS.
- i. Select and analyze internal control samples.

2. MGC Branch Supervisors and Meat Graders at the Point of Production will:

- a. Ensure contractors comply with all microbiological sampling requirements of:
 - i. FSIS Directive 10,210.1, "Unified Sampling Form" Amendment 1 (Form 10,210-3) and Amendment 3, (pages 23 and 25).
 - ii. FSIS Directive 10,010.1 "Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef, except the sample will be frozen prior to shipping. FSIS Directives are available at:
 - http://www.fsis.usda.gov/OPPDE/rdad/FSISDir10000.htm
 - iii. Applicable MGC Branch Instructions and other contractual requirements.
- b. Approve the work area, sample collecting equipment, and related supplies.
- c. Ensure that only sanitized equipment and supplies are used for sample withdrawal and preparation.
- d. Freeze the refrigerant packs used in FSIS shipping containers.
- e. Maintain adequate sample control measures at all times to prevent tampering.

3. Designated Office of Field Operations (OFO) employees will:

- a. Monitor movement of samples submitted to the AMS and FSIS Laboratories.
- b. Ensure analysis results are submitted to Area Office (AO) personnel in a timely manner.
- c. Charge additional laboratory analysis fees to applicants with presumptive or confirmed positive samples, in accordance with MGC Instruction 428.
- d. Manage and maintain Laboratory Analysis Files.

AMS Laboratory

The AMS Laboratory will analyze one-pound samples for Standard Plate Count, Total Coliforms, *E. coli*, *Salmonella*, and Coagulase Positive *Staphylococci*.

The AMS Science and Technology (S&T) Laboratory requires that the one-pound Original and the one-pound Reserve samples be split into one-half pound samples and flattened into bricks ¾ inch to 1 inch thick. Therefore, a total of seven one-half pound samples (two one-half pound

Original samples, two one-half pound Reserve samples and 3 one-half pound Temperature samples) will be collected during each production day.

1. Sample Selection, Collection and Preparation

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Samples may be obtained from any box selected for fat analysis, net weight, etc. Samples shall be selected and prepared as follows:

- a. For bulk ground product Samples shall be taken from the core of the primary container (box, chub, loaf, etc.). For chubs, use a sterile knife to remove the outer packaging. Cut the ends of the chub off and expose the chub by cutting the plastic film from one end to the other, taking sufficient care to avoid contaminating the meat product. Using a sterilized spatula or knife (do not use the same knife used to cut the chub open), split the chub lengthwise. Remove the required amount of ground product from the center of each bisected chub with either a spatula or sterile glove covered hand. Avoid ground product that is positioned immediately adjacent to the casing, bag, box, etc. Place samples directly into the sterile sample containers and flatten into bricks ¾ inch to 1 inch thick.
- b. For patty product In an individual quick freeze process, patties must be selected before freezing. To comply with AMS Laboratory sample requirements, a total of seven, one-half pound (3 patties) packages will be collected and flattened into ¾ to 1 inch thick bricks per production day. The Original and Reserve samples will be comprised of approximately one-pound of product that is split into two one-half pound packages. Each package will contain 3 patties. The Temperature samples will consist of three packages that contain one-half pound of product (3 patties) per package.

Note: Select an adjacent loaf, bag, chub, or patty if the primary selected sample is inadvertently contaminated during the withdrawal and preparation process.

Immediately place the Original, Reserve, and Temperature samples into a freezer capable of rapidly reducing the temperature to 0° F (-17.8° C) within 24 hours. Dry ice may be used, as long as; **the dry ice does not come into direct contact with the product.** (Example: the sample must be placed in a sterile plastic bag, then wrapped in a paper product such as paper towels, butcher paper, etc., for protection.) **Liquid nitrogen or other quick freeze processes are not acceptable.**

2. Sample Shipment

- a. Conduct a temperature examination on a Temperature sample to ensure that the samples have reached 0°F.
- b. Prepare the Laboratory Sampling Form for Meat Products, MGC-110 (Exhibit A).
 - 1. Ensure that the telephone and facsimile (fax) numbers and the electronic mail (e-mail) address of the designated OFO staff members are correct and included on the "Send Lab Results To" section of the Form.
 - 2. E-mail or fax a copy of the completed MGC-110 to the appropriate Area Supervisor, Area Office Assistant, and designated OFO members at:
 - a. Email <u>Pat.Griffith@usda.gov</u>, <u>Cindy.Shattuck@usda.gov</u>, <u>JamesA.Jones@usda.gov</u>, <u>and Lucille.Lucero@usda.gov</u>.
 - b. Fax (303) 294-7523.
 - c. Phone (303) 294-7676.
 - 3. Place a copy of the completed MGC-110 in the side pouch of the Official USDA Meat Grading Sample Bag (Sample Bag) and close.



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- c. Place the Original sample and a Temperature sample into the Sample Bag and secure for shipment (step-by-step instructions are on the bag). If the Original sample was lost or unusable, place the Reserve sample and one Temperature sample into the shipping container.
- d. Wrap the Sample Bag with a paper buffer, place the Sample Bag into the polyfoam mailer, place frozen refrigerant packs or dry ice around each sample and fill in the open space with dry ice and paper products to ensure that the sample maintains temperature throughout shipment.
- e. Securely close the mailer and ship to: USDA AMS S&T FLS

National Science Laboratory 801 Summit Crossing Place, Suite B Gastonia, North Carolina 28054

Phone (704) 867-3873 Fax (704) 853-2800

Do not use tape to close the mailer or apply a shield stamp to the mailer.

Note: The S&T Laboratory requests that if no samples are going to be mailed on Friday (for receipt by the Laboratory on Saturday) to notify them, so that they may schedule their staff accordingly. This should be done on a plant by plant basis.

3. Sample Receipt

- a. The laboratory will receive one-pound samples on Monday through Saturday, except on select Federal Holidays (New Years Day, July 4th, Labor Day, Thanksgiving and Christmas).
- b. If samples are not suitable for testing, S&T will contact a designated OFO staff member immediately by phone or e-mail, and will send a follow-up notification by fax.
 - 1. Phone (303) 294-7676.
 - 2. E-mail <u>Pat.Griffith@usda.gov</u>, <u>Cindy.Shattuck@usda.gov</u>, <u>JamesA.Jones@usda.gov</u>, and <u>Lucille.Lucero@usda.gov</u>.
 - 3. Fax (303) 294-7523.
- c. One of the designated OFO staff members will then contact the appropriate AO and request that the Reserve sample(s) be submitted to the Laboratory for analysis.

4. Reporting Results

- a. The S&T Laboratory will transmit test results electronically to the designated OFO staff members by 5:00 PM EST, Monday through Friday.
- b. Test results completed during a weekend will be transmitted no later than 9:00 AM EST of the following Monday or first official business day of the week.
- c. In case of network problems, the laboratory will fax the test results to the designated OFO staff members at (303) 294-7523.
- d. Designated persons will be allowed limited access to the Laboratory Analysis Files accessible at: \\SDENVLS0000A\LabAnalysisFiles\CompleteReports.

5. Remaining Samples

Once the lot has been shipped the Meat Graders will return any corresponding Reserve and Temperature samples to the contractor.

FSIS Laboratory

The FSIS Laboratory will analyze one-pound samples for E. coli O157:H7.

1. Sample Collection and Preparation

- a. Ensure contractors comply with:
 - i. FSIS Directive 10,210.1, "Unified Sampling Form" Amendment 1 (Form 10,210-3) and Amendment 3 (pages 23 and 25).
 - ii. FSIS Directive 10,010.1 "Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef, except the sample will be frozen prior to shipping. FSIS Directives are available at: http://www.fsis.usda.gov/OPPDE/rdad/FSISDir10000.htm
 - iii. Applicable MGC Branch Instructions and other contractual requirements.
- b. Samples may be obtained from any box selected for fat analysis, net weight, etc.
- c. Collect one-pound Original, one-pound Reserve, and one-pound Temperature samples from a predetermined location during the production day (cleanup to cleanup).
- d. Immediately place samples in a freezer capable of rapidly reducing the temperature to 0°F (-17.8° Celsius) within 24 hours. Liquid nitrogen or other quick freeze processes are not acceptable. DO NOT USE DRY ICE FOR FREEZING FSIS SAMPLES!

2. Sample Shipment

- a. Perform a temperature examination on the Temperature sample to ensure that the samples have reached 0°F.
- b. Complete FSIS Unified Sampling Form 10,210-3, according to FSIS Directive 10,210.1, "Unified Sampling Form" Amendment 1.
- c. Samples may be shipped Monday through Friday; however, samples shipped on Friday (for arrival at the laboratory on Saturday) **must** contain the special Saturday mailing label.
- d. Send mailers by an overnight carrier to: USDA, FSIS, OPHS

Eastern Laboratory

Russell Research Center, Suite 205

950 College Station Rd Athens, Georgia 30604

e. FSIS forms and boxes may be ordered by contacting one of the designated employees at the OFO.

3. Sample Receipt

- a. The FSIS Laboratory will receive samples Monday through Saturday, except on Federal Holidays.
- b. If samples are not suitable for testing, FSIS will contact a designated OFO staff member immediately via phone or e-mail, and send a follow-up notification by fax.
 - 1. Email <u>Pat.Griffith@usda.gov</u>, <u>Cindy.Shattuck@usda.gov</u>, <u>JamesA.Jones@usda.gov</u>, and Lucille.Lucero@usda.gov.
 - 2. Fax (303) 294-7523.
 - 3. Phone (303) 294-7676.
- c. A designated OFO staff member will then contact the appropriate AO and request that the Reserve sample(s) be submitted to the FSIS Laboratory for analysis.



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4. Reporting Results

- a. The FSIS Laboratory will transmit test results electronically to designated OFO staff members.
- b. In case of network problems, the FSIS Laboratory will fax the laboratory results to the designated OFO staff members at (303) 294-7523.
- c. A designated staff member will provide test results to each AO in a timely manner.
- d. Designated persons will be allowed limited access to the Laboratory Analysis Files. The database may be accessed at: \\SDENVLS0000A\LabAnalysisFiles\CompleteReports

5. Remaining Samples

Once the lot has been shipped the Meat Graders will return any corresponding Reserve and Temperature samples to the contractor.

Larry R. Meadows, Chief Meat Grading and Certification Branch Livestock and Seed Program

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC CHANGE TRANSMITTAL SHEET Unified Sampling Form DIRECTIVE REVISION AMENDMENT OTHER 10,210.1 Amend. 3

I. PURPOSE

This change transmittal replaces Attachment 2 to correct typographical errors, update references, convey new sample collection and shipping procedures, and describe the new import ready to eat meat and poultry products microbiological sampling program. Also, the pages in Attachment 2 have been reorganized to eliminate gaps in page numbers. NOTE: The changes in this transmittal are effective on July 1, 2002.

II. PRINCIPAL CHANGES (new page numbers cited here)

- A. Pages 17 20: Added project numbers for follow-up sampling and reduced level sampling and updated references.
- B. Page 19: Corrected title of program.
- C. Page 21: New RTE sampling program for imported RTE meat and poultry products, replacing ME13 and MT09.
- D. Page 22: Updated references.
- E. Pages 23 25: Added additional sample collection guidelines to allow for late shift and weekend sampling of raw ground beef for *Escherichia coli* O157:H7 testing.

III.CANCELLATION

This transmittal is cancelled when contents have been incorporated into FSIS Directive 10,210.1.

Philip S. Derfler

Deputy Administrator
Office of Policy, Program Development and Evaluation

FILING INSTRUCTION

Remove Old Pages

Insert New Pages

15-38

Offices, FSIS Laboratories

15-38 (pages 36 and 38 reserved)

DISTRIBUTION: Inspection Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, Import

OPI: OPPDE

Product Sampling - Microbiology MT03/MT04 - Raw Ground or Comminuted Beef or Veal (Beef or Veal Only) Federal Program

	Federal Program
Project Number	MT03/MT04
Program Title	E. coli O157:H7 Raw Ground or Comminuted Beef or Veal
Drogram Dates	Ongoing
	E. coli O157:H7
Product to Sample	Raw Ground or Comminuted Beef or Veal Products including Ground Beef, Hamburger, Beef Patties, Beef Patty Mix, etc.
Collection Instructions	SEE GUIDELINES ON PAGE 25. At a RANDOML Y selected day, shift, and time within the sample collection timeframe indicated in block 4 of FSIS Form 10,210-3, ASEPTICALLY collect a RAW, UNFROZEN 1 pound sample prior to packaging and freezing. Use the sterile sample bag that has been provided to you for this purpose. Close the bag securely. Label the bag with the provided sample identification
Sumple Teeques	Fill out the form according to the instructions. Place the sample request form in a plastic bag and place the plastic bag into the shipping container with the samples. If product requested is unavailable for sampling, complete Block 33 and mail the form to the laboratory listed in Block 9 and on the PRE-ADDRESSED LABEL.
Establishment Management Notification	Give establishment management sufficient notification of sampling so that the sampled product may be held. Remind establishment management of its option to hold the sampled lot.
Shipment	SEE GUIDELINES ON PAGE 25. Ship to the laboratory listed in Block 9 of the sample request form and on the PRE-ADDRESSED LABEL. Ship via overnight courier the same day as collected, or as soon as overnight courier is available, as described in the guidelines on page 25. Use sufficient FROZEN COOLANT to keep samples cold during transit. If samples are collected on a Friday, designate SATURDAY DELIVERY. Do not ship samples on the day before a Federal holiday.
References	FSIS Directive 10,230.2 FSIS Directive 10,010.1

Additional Shipping Guidelines for MT03, MT04, MT05, and MT06:

FSIS inspection program personnel may collect a scheduled MT03, MT04, MT05, OR MT06 sample at **any** randomly selected day, shift and time within the sample collection timeframe on FSIS Form 10,210-3. Shipping would have to occur at the **next available** Federal Express pickup time, as follows:

- 1. Samples collected **before** Federal Express pickup Monday through Friday should be held **refrigerated** until shipped that **same** day.
- 2. Samples collected after Federal Express pickup Monday through Thursday should be held refrigerated overnight and shipped the next day.
- 3. Samples collected during the **weekend** (after Federal Express pickup Friday through Sunday night) should be **frozen** and shipped on **Monday**. Note: If Monday is a holiday that Federal Express does not pick up samples, they may be held frozen until shipping on Tuesday.
- 4. Inspection program personnel should ensure that sample integrity and security is maintained at all times.
- 5. Samples not meeting the above shipping criteria will be discarded upon receipt at the laboratory.

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS	10,210.1 Amendment	6-10-99
DIRECTIVE	-	

UNIFIED SAMPLING FORM

I. PURPOSE

This directive provides instructions to inspectors for the use of a unified sampling form to be used for all directed sampling programs (microbiological, chemical, and residue). This directive transmits sample copies of FSIS Form 10,210-3 and instructions for completing the form, and specific instructions for each individual sampling project. The sampling projects and the new form establish a uniform system for sample collection and transmittal of samples to laboratories. The use of the new form and system will facilitate the eventual electronic transfer of sampling requests and the tracking of samples in the laboratories.

II. RESERVED

III. REFERENCES

Sections 309.16, 310.21, 317.300, 318.19, 319.104, 319.105 and 381.74, 381.409 of the MPI Regulations, the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act.

IV. RESERVED

V. GENERAL INSTRUCTIONS FOR INSPECTION PERSONNEL

A. FSIS Form 10,210-3 is a one page form (Attachment 1). When the form is sent to inspectors certain blocks will be pre-printed with information specific to the sample (i.e., microbiology, food chemistry, or residue) to be collected. For example, the establishment number, sampling project number and/or sampling project name, and sample collection time window will be pre-printed on Part I of the form (see Form Completion Instructions and examples in Attachment 1 for specific block entries).

B. When a sample request form is received, sample collectors must refer to the specific instructions regarding sample collection for the given project number and/or project name provided in Attachment 2 (microbiology), Attachment 3 (chemistry), and Attachment 4 (residue). Sample

collectors will complete Part II of the form and send it with the sample to the specified laboratory. If for any reason requested samples are not collected, sample collectors should complete blocks 29-33 of Part II and send the form to the specified laboratory.

/s/

Philip S. Derfler

Deputy Administrator Office of Policy, Program Development and Evaluation

Attachment 1-- FSIS Form 10,210-3 and instructions

Attachment 2 -- Microbiology Samples

Attachment 3 -- Food Chemistry Samples

Attachment 4 -- Residue Samples

DISTRIBUTION: Inspection Offices; T/A	OPI: OPPDE
Inspectors;	
Plant Mgt; T/A Plant Mgt; TRA; ABB; PRD,	
Import Offices	

FSIS Directive 10,210.1 Attachment 1

Instructions for Completing the Requested Sample Programs Form

Each block is explained below. If the information is only for one of the sampling programs, then the instructions for that block will begin with the specific sampling program (Chemistry, Microbiology, or Residue). If no specific program is mentioned, then the instructions are applicable for all three sampling programs.

Part I

Blocks are pre-printed with information specific to the type of sample to be drawn. Check the following boxes to verify accuracy.

- Block 1: Information is preprinted.
- Block 2: Information is preprinted.
- Block 3: Determine if the printed establishment number is correct for the establishment where the sample is to be collected.
- Block 4: Note the time frame during which to collect the requested sample.
- Block 5: Information is preprinted.
- Block 6: Information is preprinted.
- Block 7: Information is preprinted.
- Block 8: Check the accuracy of the name and address for the establishment where the sample is to be collected.
- Block 9: Chemistry Enter the name, address, and code of the laboratory to which the sample is to be sent (e.g., FSIS TSL or Accredited laboratory).

 Microbiology and Residue Information is preprinted.
- Block 10: Residue Note which slaughter class to sample.
- Block 11: Residue Note from which species to collect the sample.
- Block 12: Residue Note what tissue to sample.
- Block 13: Analysis requested should be consistent with the box checked in the heading.

 Microbiology Information is preprinted.
- Block 14: **Microbiology** and **Residue** Note the project number. Refer to that project in this document for specific information on the type of product to sample as well as how much product to collect for the sample.
- Block 15: For Imports Only Enter the country of origin.
- Block 16: For Imports Only Enter the country code.
- Block 17: For Imports Only Enter the foreign establishment number.
- Block 18: Follow instructions in this block. Additional information about the sample may be needed for specific project purposes. Fill-in all requests for information that are in this block.

Part II

The sample collector is required to supply certain requested information. The information the sample collector is responsible for supplying is to be written or typed in the blocks.

Block 19: Enter the date the sample was collected.

Block 20: Enter the date the sample was sent to the laboratory (note the laboratory address pre-printed in Block 9 in Part I).

Block 21: Microbiology - IF REQUESTED in the specific project instructions, enter the product temperature at the time the sample was collected. Take the sample temperature as indicated in the project directions, DO NOT CONTAMINATE THE SAMPLE WHEN TAKING THE TEMPERATURE. Clean and sanitize the temperature monitoring device prior to use.

Block 22: Check whether or not the product was held by the establishment pending receipt of this laboratory analysis result.

Block 23: For Imports Only - Enter the serial number of Form FSIS 9540-1.

Block 24: Residue - Enter the lot number.

For Imports Only - Enter the lot number of the collected sample from Form FSIS 9540-1.

Block 25: For Imports Only - This block is self-explanatory.

Block 26: Enter the producer/dealer/owner name and complete address. If it is the same as the information pre-printed in Block 8, enter the words, "Same as Block 8".

Block 27: Microbiology and Residue - Enter all animal identification (e.g., ear tag, back tag, tattoo).

Block 28: Additional information about the sample may be needed for specific project purposes. Complete all requests for information that are in this block. **Residue** - Enter the lot size.

Imports - Enter the product code.

Block 29: Sample collector, enter your signature in this block.

Block 30: Print or type the name of the sample collector who signed Block 29.

Block 31: Enter the badge number of the sample collector who signed Block 29.

Block 32: Enter the telephone number of the establishment where the sample was collected.

Block 33: This is to be filled-in only in the event that a sample is **NOT** submitted.

Part III

This section is to be filled-in only by the receiving laboratory listed in Block 9.

Internal lab code

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE



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33. IF THE REQUEST	TED SAMPLE(S) ARE	NOT COLLECTED,	CHECK OF	THE APPROPRIATE R	EASON & RETURN	THIS FORM TO TH	E LAB INDICATED ABOVE.	
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FOR LABORATORY USE ONLY

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LAB CODE		REVIEWED BY					
FOOD (CHEMISTRY SA	MPLE LABORA	TORY RESULT	S FORM	INTERNAL LAB NUN	1BER	
TOTAL PROTEIN	MEAT PROTEIN	TOTAL WATER	ADDED WATER	+ ADD. SUBS.		14808470	
01 %	02/60 %		04 %		INSPECTOR REQUESTED TEST	TEST CODE	TEST RESULT
- ADD. SUBS.	SALT	TOTAL FAT	MAX. INT. TEMP.	SODIUM NITRITE		1201 0002	TEST RESULT
06 % SODIUM NITRATE	07 %	 	09 %	10 ppm			
11 ppm	PHOSPHATE	M/P RATIO	BRINE CONTENT	PERCENT BONE			
FAT BY DIFF.	SULFITE	ASCORBATE	FAT + ADDED WATER	26 % CALCULATED PFF			
30 %	31 ppm		_				
		34 ppm dditional laboratory find					
DATE ANALYSIS STA	ARTED	DATE ANALYSIS CO	MPLETED	SRC	wc	ANALYST(S) CODES	·
LAB CODE		REVIEWED BY					
		WE VICTUED BY					
PROTEIN F	AT FREE (PFF)	SAMPLE LABOR	RATORY RESU	JLTS FORM	INTERNAL LAB NUM	BER	
TEST	RESULTS	•					
		FOR LABORATORY L	JSE ONLY:				
01 - Total Protein	%						
08 - Total Fat	%	-					
60 - PFF Meat	%						
68 - Calculated PF	F o						
DATE ANALYSIS STA		DATE ANALYSIS CO	MPI ETED	SRC	\A/C		
			*** ****	anc	WC	ANALYST(S) CODES	
LAB CODE		REVIEWED BY					***

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE

10,010.1

2-1-98

Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef

I. PURPOSE

This Directive provides FSIS inspection personnel and compliance officers instructions for selecting, collecting, and submitting raw ground beef samples to be tested for *Escherichia coli* O157:H7. Also, attachment 1 provides the background of the testing program and questions and answers addressing issues such as the reporting of results and actions taken by the Agency.

II. CANCELLATION

FSIS Notice 50-94

III. REFERENCES

Federal Meat Inspection Act FSIS Directives 10, 230.2 and 10,210.1

IV. RESERVED

V. TERMINOLOGY

The following terms apply for purposes of the testing program in this directive:

<u>Sampled Lot</u> All raw ground beef products produced between performance of complete cleaning and sanitization procedures for all equipment used in handling or processing a raw ground beef product.

Raw Ground Beef Products Raw comminuted (chopped or ground) meat food products made from cattle carcasses (beef and/or veal), such as ground beef, hamburger, veal patties, and beef patty mix, that may be distributed to consumers as such. (Sampled products may contain beef derived from advanced meat recovery systems and/or Mechanically Separated Beef, but these products are not to be sampled as such. Nor are products that contain another type of livestock product in addition to beef (for example, fresh beef and pork sausage).)

<u>Positive Sample</u> A sample is positive for E. coli O157:H7 when it is positive for E. coli O157 and (1) the H7 antigen test is positive or (2) the H7 antigen test is nonspecific or the culture is nonmotile and either toxin or one or more toxin genes are present.

VI. SAMPLE COLLECTION INSTRUCTIONS AT INSPECTED ESTABLISHMENTS

- A. When the Office of Public Health and Science (OPHS) transmits FSIS Form 10,210-3 under sample project code MT03, inspection personnel collect samples in accordance with the instructions for MT03 found in FSIS Directive 10,210.1.
- B. Unless otherwise directed by OPHS through supervisory channels or an establishment has had a positive test result within 6 months, inspection personnel should not collect samples at establishments that either:
- 1. Conduct routine daily testing of their raw ground beef products or boneless beef to be used in raw ground products for *E. coli* O157:H7,
- 2. Require suppliers of boneless beef to certify that each lot received has been tested and found negative for *E. coli* O157:H7, or
- 3. Use validated pathogen reduction interventions on beef carcasses, routinely verify the interventions effectiveness periodically through testing for *E. coli* O157:H7, and prevent the use of boneless beef or carcasses from outside sources.
- C. To verify that establishments have implemented one or more of the above, inspection personnel ensure that establishments have a testing protocol on file, testing records documenting positive and negative results, or certificates. Inspection personnel also can observe the operation of pathogen reduction interventions and review related records. Upon receiving the FSIS Form 10,210-3, inspection personnel should review the records to determine that no positive results have been reported within 6 months. This record review should be done within the time period for sample collection indicated on the form.
- D. If samples are not collected, inspection personnel complete block 33 of FSIS Form 10,210-3.
- E. If notified that a sample is confirmed positive for *E. coli* O157:H7, inspection personnel:
- 1. Condemn the sampled lot, unless it is fully cooked in accordance with 9 CFR 318.23 or processed in an equivalent manner to that required by the regulations.

- 2. Collect subsequent samples from new lots on a daily basis in accordance with the instructions for MT04 found in FSIS Directive 10,210.1 until 15 consecutive ground beef samples have tested negative for *E. coli* O157:H7. OPHS will issue the necessary number of FSIS Form 10,210-3 under sample project code MT04 to the appropriate IIC.
 - F. Direct questions through supervisory channels to the Technical Center.

VII. SAMPLE COLLECTION INSTRUCTIONS AT RETAIL OUTLETS

- A. OPHS will transmit FSIS Form 10,210-3 under sample project code MT05, to the Assistant District Manager for Enforcement at the appropriate District Office, for the week that samples are to be collected.
- B. Compliance officers should randomly select the retail outlet from which a sample will be collected. An effort should be made to visit retailers at a time when the retail outlet is grinding product.
- C. Compliance officers should collect samples in accordance with the instructions for MT05 found in FSIS Directive 10,210.1.
- D. If samples are not collected, compliance officers complete block 33 of FSIS Form 10,210-3.
- E. If notified that sample is confirmed positive for *E. coli* O157:H7, compliance officers collect samples on a daily basis in accordance with the instructions for MT06 found in FSIS Directive 10,210.1 until 15 consecutive ground beef samples have tested negative for *E. coli* O157:H7. OPHS will issue the necessary number of FSIS Form 10,210-3 under sample project code MT06 to the appropriate compliance officer.

VIII. RESPONSIBILITIES OF IMPORT INSPECTION PERSONNEL

A. When the import inspector is instructed to sample imported raw ground beef products for *E. coli O157:H7* testing, he/she should collect samples in accordance with instructions for project MT08 found in FSIS Directive 10,210.1, and submit FSIS Form 10,210-3 with each sample. The imported product subject to *E. coli* O157:H7 testing is represented by the following product codes: BABXK2 (ground fresh beef greater than 10 pounds), BABXK3 (ground fresh beef 10 pounds or less), and BABXK4 (beef patties).

- B. If the sample is confirmed positive for *E. coli O157:H7*, the foreign establishment will be placed on intensified inspection. The import inspector will collect samples form the next 15 consecutive shipments of ground beef shipped to the United States from that establishment. In the case of shipments form Canada, the establishment may request the Canadian Food Inspection Agency to sample shipments prior to shipping and to certify negative results for *E. coli O157:H7* on the health certificate.
- C. Import inspection personnel will not collect samples of imported raw ground beef if the shipment is accompanied by a health certificate containing the following statement: \Box This product has been subject to an E. coli O157:H7 prevention and/or testing program that was monitored by the inspection system of the exporting country. \Box This certifies that the exporting establishment meets the criteria listed in paragraph VI. B, including the requirement that establishments have not had a positive test result within the last 6 months.

/s/ Maraget OK. Glavin

Deputy Administrator
Office of Policy, Program Development and Evaluation

Attachment